DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
M23781

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: (510) 337-6700

VIA FEDERAL EXPRESS

Our Reference: 29-50967

February 10, 1999

Mark P. Mayo, General Managing Partner
Mayo Dairy
11923 East Childs Avenue
Le Grand, California 95333-9717

WARNING LETTER

Dear Mr. Mayo:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on January 19, 20, and 25, 1999, by Food and Drug Administration (FDA) Investigator Thomas W. Gordon have revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act. On August 18, 1998, you consigned a dairy cow (identified by USDA laboratory report number 391457) to be slaughtered as human food. This cow, which was delivered for introduction into interstate commerce by your firm, was adulterated by the presence of an illegal antibiotic drug residue. USDA analysis of tissues from this animal revealed the presence of gentamicin in the kidney at 3.80 parts per million (ppm). A tolerance level for gentamicin has not been established for the edible tissues of cattle.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply.

For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.

2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

3. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.

4. You lack an adequate system for assuring animals have been treated only with drugs which have been approved for use in their class of animal or species.

5. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

You are adulterating the drug Legacy brand of gentamicin sulfate within the meaning of Section 501(a)(5) of the Act when you do not use this drug in conformance with prescribed labeling. Your veterinarian prescribed the gentamicin sulfate for medicating your calves only. The prescribed labeling on the drug includes a requirement for a withdrawal time of eighteen months prior to slaughter. Your practice of medicating lactating dairy cows with gentamicin sulfate, coupled with a failure to comply with the withdrawal time, is likely the cause of the gentamicin residue in the cow you sold for slaughter.

Your use of Bimeda brand penicillin G procaine is not in accordance with approved labeling. Labeling for Bimeda specifically states it is to be used for intramuscular administration only. Your practice of mixing Bimeda with Dexamethasone to create a solution to medicate your cows for pink-eye is an unapproved use for which safety and efficacy have not been established and constitutes manufacturing a new animal drug, which requires the submission of a New Animal Drug Application for FDA approval.

Your use of Maxim 100 brand oxytetracycline hydrochloride is not in accordance with approved labeling. Labeling for Maxim 100 specifically states it is to be used to treat non-lactating dairy cattle, and it is only to be administered intravenously. Your practice of mixing Maxim 100 oxytetracycline with water to create a uterine infusion to medicate your cows is an unapproved use for which safety and efficacy have not been established and constitutes manufacturing a new animal drug, which requires the submission of a New Animal Drug Application for FDA approval.

Your use of the drug Tetrasol brand tetracycline hydrochloride soluble powder is not in conformance with approved labeling. Product labeling states that it is to be administered in the drinking water of calves for the treatment of scours and pneumonia. Your practice of placing Tetrasol in a gelatin capsule to create a uterine bolus is an unapproved use for which safety and efficacy have not been established and constitutes manufacturing a new animal drug, which requires the submission of a New Animal Drug Application for FDA approval.

Your use of drugs for treating your dairy cows does not conform to the labeling instructions. Failure to comply with the label instructions on drugs used to treat animals makes the drugs unsafe for use.

We request that you take prompt action to ensure that dairy cows and calves which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal into interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal to be slaughtered into food for human consumption where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Your firm has established a history of offering animals for sale for human food use which have been found to be adulterated with drug residues. According to USDA analytical reports, during the period of August 24, 1989, through August 19, 1998, your firm sold two cows which contained violative levels of gentamicin and tetracycline. During this same period, you sold five calves which were found to be CAST positive by USDA analysis due to the possible presence of violative levels of antibiotics. As a result of the violative residues, inspections were conducted of your dairy on November 6, 1992, and on June 1, 1993. During each of

those inspections you were warned that it is illegal to market cull dairy cattle which contain illegal levels of antibiotics. A Warning Letter, dated August 17, 1993, was issued to you as a result of these inspections. Also, USDA sent you a letter for each of the cull cows and calves in which USDA analysis found violative levels of drug residues. You have failed to take adequate corrective action. It is your responsibility to ensure that all requirements of the Act are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen (15) days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Thomas W. Gordon, Investigator, Food and Drug Administration, 2202 Monterey Avenue, Suite 104E, Fresno, California 93721.

Sincerely yours,

Charles D. Moss
Acting District Director

for Patricia C. Ziobro
District Director
San Francisco District

cc: [redacted]